

## **DETAILED OFFICE ACTION**

### ***Withdrawal of Final Rejection***

The Final Rejection of September 29, 2008 is withdrawn to enter the following new grounds of rejection. MPEP § 706.07(e). Accordingly, the submission of February 23, 2009 is entered as a matter of right.

### ***Title***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Rejections Under 35 US 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which the specification does not describe so as to reasonably convey to one skilled in the relevant art that the inventors, when the application was filed, had possession of the claimed invention. This is a new matter rejection.

There is no support in the application as filed for the added limitations in claim 2 of the definitions of R1, R2, L, Y, and the added limitations to the definitions of

carbocyclic aryl, carbocyclyl and heterocyclyl. Applicants assert that support for these limitations (Amendment filed Oct. 16, 2007, at page 117, *inter alia*) “can be found throughout the specification, and at least within the examples ...” The specification contains a “laundry list” of these variables, which would not reasonably lead one of skill in this art to select the specific groups of variables now recited.

Introduction of claim changes which involve claim narrowing by introducing elements or limitations not supported by the as-filed disclosure is a violation of 35 USC 112, first paragraph, written description requirement. See *Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible disease/disorder does not constitute a written description of every species in a genus; it does not “reasonably lead” one skilled in the art to any particular species or sub-genus).

The application as filed does not disclose the proposed sub-genera in *ipsis verbis*. *Ipsis verbis* disclosure is not necessary to satisfy section 112 written description requirement. Instead, the disclosure need only reasonably convey to persons skilled in the art that applicant had possession of the subject matter in question. *In re Edwards*, 196 USPQ 465, 467 (CCPA 1978). In other words, the question is whether the present “application provides adequate direction which reasonably [would lead] persons skilled in the art” to the sub-genera of the proposed claim. As was remarked by the Court of Customs and Patent Appeals more than forty years ago and remains true today:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. [Applicants] are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

*In re Ruschig*, 154 USPQ 118, 122 (CCPA 1967).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1:**

- The terms "heterocycloxy" and "heterocyclthio" are not understood. They may mean a heterocyclyl group that has the identified chalcogen ring member, or they may mean a chalcogen group that is further substituted by a heterocyclyl group. The same is true of "heterocyclysulfonyl" and other variants. The terms further fail to identify ring size or ring members. The specification does not clarify these terms.
- The phrase "mono-carbocyclic aryl amino substituted by ..." is not understood. It may be interpreted to mean an amino that has one mono-carbocyclic aryl and the second amino substituent is the named substituent. Or may be interpreted to mean an amino that has one mono-carbocyclic aryl and the named substituent substitutes the mono-carbocyclic aryl group. The term further fails to identify the ring size. The specification does not clarify this term.
- The phrase "di-carbocyclic aryl amino" and its variants are not understood. It may be interpreted to mean an amino that has two such carbocyclic aryl groups on the

nitrogen, or may be interpreted to mean an amino that has one aryl group substituted with two carbocyclic groups. The specification does not clarify this term.

- The difference between "cycloalkyl" and "carbocyclyl" is not understood. The specification does not clarify these terms.
- The phrase "R5 and R1 together with the nitrogen [*sic*] they are bonded form a heterocycl" is not understood. It is ungrammatical. R5 and R1 are not bonded to the same N. The specification does not clarify this term.

### ***Rejections Under 35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of claims under 35 U.S.C. 103(a), the examiner presumes that subject matter of the various claims was commonly owned when any inventions covered therein were made absent evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned when a later invention was made so the examiner may consider applicability of

Art Unit: 1624

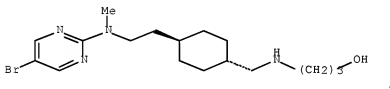
35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35

U.S.C. 103(a).

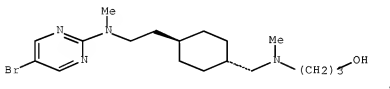
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

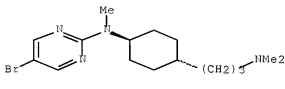
Claims 2, 75, 103 and 112 are rejected under 35 U.S.C. 103(a) over Ackerman, et al., US Pat. No. 7,012,077, entitled to the filing date of Dec. 5, 2002, describes RN 553677-39-7, 1-Propanol, 3-[[[trans-4-[2-[(5-bromo-2-pyrimidinyl)methylamino]ethyl]cyclohexyl)methyl]amino]-



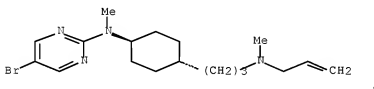
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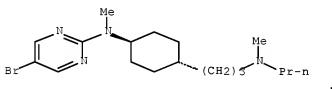
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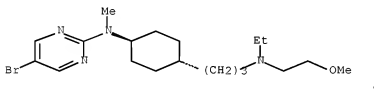
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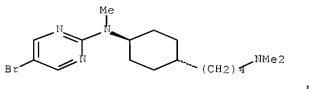
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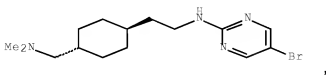
RN 553676-57-6, 2-Pyrimidinamine, 5-bromo-N-[trans-4-[3-[ethyl(2-methoxyethyl)amino]propyl]cyclohexyl]-N-methyl-,



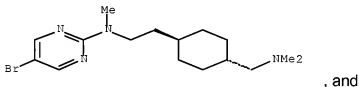
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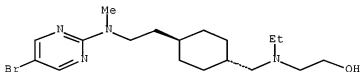
RN 553677-00-2, 2-Pyrimidinamine, 5-bromo-N-[2-[trans-4-(dimethylamino)methyl]cyclohexyl]ethyl]-,



RN 553677-02-4, 2-Pyrimidinamine, 5-bromo-N-[2-[trans-4-[(dimethylamino)methyl]cyclohexyl]ethyl]-N-methyl]-,



RN 553677-37-5, Ethanol, 2-[[[trans-4-[2-[(5-bromo-2-pyrimidinyl)methylamino]ethyl]cyclohexyl]methyl]ethylamino]-,



The presently claimed compounds are lower alkyl homologs or position isomers of the Ackerman compounds, and obvious thereover for the same utility.

It would have been obvious to one of ordinary skill in the art when the present invention was made to modify the Ackerman compounds to prepare structural homologs

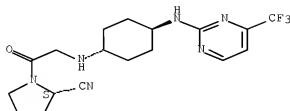
and position isomers thereof. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous and position isomeric compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous and position isomeric to prior art compounds are *prima facie* obvious, absent a showing of unexpected results.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

*In re Payne*, 203 USPQ 245, 254 (CCPA 1979). See also *In re Papesch*, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed in MPEP § 2144) for an extensive case law review pertaining to obviousness based on close structural chemical compound similarity. See also MPEP § 2144.08, ¶ II.A.4(c). Compounds that are homologs (compounds differing regularly by successive addition of the same chemical group, e.g., by CH<sub>3</sub>- groups) and position isomers (compounds differing by an adjacent or near adjacent functional group), as here, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 195 USPQ 426 (CCPA 1977).

Claims 2, 103 and 112 are rejected under 35 USC 103(a) over Yasuda, et al., WO 2002030891, published 20020418, describing a dipeptidyl peptidase IV inhibitor, RN 412915-48-1, 2-Pyrrolidinecarbonitrile, 1-[2-[[trans-4-[[4-(trifluoromethyl)-2-pyrimidinyl]amino]cyclohexyl]amino]acetyl]-, hydrochloride,





●<sub>2</sub> HCl

. The presently claimed compounds are lower alkyl homologs or position isomers of the Yasuda compound, and obvious thereover for the same utility. See the discussion above of the obviousness of lower alkyl homologs or position isomers of prior known compounds.

### ***Objected Claims***

Claims 57, 58, 63, 64, 68, 72, 80, 81, 86, 87, 91, 92, 95, 96 and 101 are objected to as dependent on a rejected base claim, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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